

REMARKS

Applicants respectfully request entry of the forgoing amendments. Applicants submit that the foregoing amendments do not introduce new matter.

Applicants believe claims 1 through 26 are in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully Submitted,



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Date

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Signature

ELIZABETH Grannell

Printed Name

Please amend claims 1, 5 through 7, 9, and 15 as set forth below. Applicants note that all claims currently pending in the application are shown below for clarity.

1. (Twice Amended) An active agent dosage form comprising:
a first layer comprising an amount of swellable polymer [sufficient to swell said first layer to a first length, said first length being sufficient to facilitate retention of said active agent dosage form within a stomach of a subject], said amount being sufficient to swell said first layer such that the active agent dosage form is retained within a stomach of a subject;
a second layer laminated with the first layer at a common surface, said second layer comprising a therapeutic amount of an active agent and being formulated to [limit expansion of said second layer to a length less than said first length] swell to a lesser extent than the first layer; and
at least one band of insoluble material circumscribing and binding together the first layer and the second layer.
2. (Amended) The active agent dosage form of claim 1, wherein the number average molecular weight of the swellable polymer is between about 100,000 and 20,000,000 grams per mole.
3. (Amended) The active agent dosage form of claim 2, wherein the swellable polymer is polyethylene oxide, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, hydroxyethyl cellulose, sodium carboxy methylcellulose, calcium carboxymethyl cellulose, methyl cellulose, polyacrylic acid, maltodextrin, pre-gelatinized starch, guar gum, sodium alginate, or polyvinyl alcohol.

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4. (Amended) The active agent dosage form of claim 1, wherein the second layer comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, a cross-linked ion exchange resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules, sodium carboxymethyl starch, sugars, and sodium chloride, and the first layer optionally comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked ion exchange resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules, sodium carboxymethyl starch, sugars and sodium chloride.

5. (Twice Amended) The active agent dosage form of claim 1, wherein the first layer swells more rapidly [and to a greater extent] than does the second layer.

6. (Twice Amended) The active agent dosage form of claim [5] 1, wherein the active agent is an antiviral, antimicrobial, antidiabetic, antihyperglycemic, hypoglycemic, antidepressant, antiobesity or antifungal active agent.

7. (Twice Amended) The active agent dosage form of claim [4] 1, wherein the second layer includes 5 to 99.99 weight percent of a swellable polymer and further includes up to 60 weight percent, inclusive, of [the] a hydroattractant.

8. (Amended) The active agent dosage form of claim 1, wherein the first layer is formulated such that the active agent dosage form is retained within the stomach for a prolonged period of time.

9. (Twice Amended) The active agent dosage form of claim [8] 1, wherein the [prolonged period of time is] first layer is formulated such that the active agent dosage form is retained within the stomach for between about 6 to 12 hours.

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10. (Amended) The active agent dosage form of claim 1, wherein the first layer comprises polyethylene oxide having a number average molecular weight of at least 100,000 grams per mole.

11. (Amended) The active agent dosage form of claim 10, wherein the active agent is an antiviral, antimicrobial, antidiabetic, antihyperglycemic, hypoglycemic, antidepressant, antiobesity or antifungal active agent.

12. (Amended) The active agent dosage form of claim 11, wherein the active agent is acyclovir, ganciclovir, ritonavir, minocycline, cimetidine, ranitidine, captopril, methyldopa, selegiline, minocycline, fexofenadine, metformin, bupropion, orlistat or a pharmaceutically acceptable salt thereof.

13. (Amended) The active agent dosage form of claim 10, wherein the active agent is metformin or a pharmaceutically acceptable salt thereof.

14. (Amended) The active agent dosage form of claim 1, wherein the second layer comprises an active agent selected from the group consisting of acyclovir, ganciclovir, ritonavir, metformin, bupropion, orlistat and minocycline, and the second layer comprises a bioerodible polymer, wherein the dosage form is formulated to release a therapeutically-effective amount of the active agent to the stomach of a subject over at least a 3 hour period.

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21. (Amended) The active agent dosage form of claim 20, wherein the liquid active agent formulation is sorbed into porous particles.
22. (Amended) The active agent dosage form of claim 21, wherein the porous particles are calcium hydrogen phosphate or magnesium aluminometasilicate.
23. (Amended) The active agent dosage form of claim 1, wherein the dosage form comprises a pH regulating agent.
24. (Amended) The active agent dosage form of claim 21, wherein the liquid active agent formulation comprises a pH regulating agent selected from organic and inorganic acids and bases.
25. (Amended) The active agent dosage form of claim 21, wherein the liquid active agent formulation comprises a chelating agent.
26. The active agent dosage form of claim 8, wherein the prolonged period of time is at least 3 hours.

comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, a cross-linked ion exchange resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules, sodium carboxymethyl starch, sugars, and sodium chloride, and the first layer optionally comprises a hydroattractant selected from low-substituted hydroxypropyl cellulose, microcrystalline cellulose, cross-linked sodium or calcium carboxymethyl cellulose, cellulose fiber, cross-linked polyvinyl pyrrolidone, cross-linked polyacrylic acid, cross-linked ion exchange resin, alginates, colloidal magnesium-aluminum silicate, corn starch granules, rice starch granules, potato starch granules, sodium carboxymethyl starch, sugars and sodium chloride.

5. (Twice Amended) The active agent dosage form of claim 1, wherein the first layer swells more rapidly [and to a greater extent] than does the second layer.

6. (Twice Amended) The active agent dosage form of claim [5] 1, wherein the active agent is an antiviral, antimicrobial, antidiabetic, antihyperglycemic, hypoglycemic, antidepressant, antiobesity or antifungal active agent.

7. (Twice Amended) The active agent dosage form of claim [4] 1, wherein the second layer includes 5 to 99.99 weight percent of a swellable polymer and further includes up to 60 weight percent, inclusive, of [the] a hydroattractant.

8. (Amended) The active agent dosage form of claim 1, wherein the first layer is formulated such that the active agent dosage form is retained within the stomach for a prolonged period of time.

9. (Twice Amended) The active agent dosage form of claim [8] 1, wherein the [prolonged period of time is] first layer is formulated such that the active agent dosage form is retained within the stomach for between about 6 to 12 hours.